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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,576	02/09/2001	Olivier Civelli	P-UC 4530	1610

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[REDACTED] EXAMINER

LI, RUIXIANG

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1646

DATE MAILED: 09/24/2002 1 4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/780,576	CIVELLI ET AL.
	Examiner	Art Unit
	Ruixiang Li	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 August 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
 - 4a) Of the above claim(s) 21-33 is/are withdrawn from consideration
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-8,10-13,15-18 and 20 is/are rejected.
- 7) Claim(s) 3,9,14 and 19 is/are objected to
- 8) Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 February 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received
 2. Certified copies of the priority documents have been received in Application No. _____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 and 13</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group I, Claims 1-6 and 12-16, in Paper No. 12 filed on 08/12/2002 is acknowledged. The traverse is on the ground that all the pending claims recite a functional relationship between ADP-glucose and the ADP-glucose receptor and examination all the claims would not be a serious burden on the Examiner. This has been fully considered but is not deemed to be persuasive because while all the claims are related to ADP-glucose and the ADP-glucose receptor, they do represent distinct inventions as set forth in the previous Office action (Paper No. 11) and search and consideration of all claims constitute an unduly burden on the Office. Nonetheless, the Examiner agrees on rejoinder of Group II with elected Group I, in view of applicants' argument and request.
2. Claims 1-33 are pending. Claims 1-20 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to a provisional application, 60/234,025, filed on September 20, 2000.

Drawings

4. The drawings, Figs. 2-5, filed on 02/09/2001, are objected by the Examiner because the drawings are illegible.

A proposed drawing correction or the corrected drawing is required in reply to the Office action to avoid abandonment of the application. The objection to the drawing will not be held in abeyance.

Information Disclosure Statement

5. The information disclosure statements filed on August 12, 2002 in Paper No.13 fail to comply with 37 CFR 1.98(a)(3) because the date on the references cited from GenBank is missing. These references will not be fully considered and will not be printed on the face of the patent resulting from this application, unless complete information is provided in a PTO-1449 form.

Claim Rejections—35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 2, 8, 13, and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a ligand, an agonist, or antagonist of the ADP-glucose receptor set forth in SEQ ID NO:2, does not

reasonably provide enablement for a method of identifying a ligand, an agonist, or antagonist of an ADP-glucose receptor with at least 70% identity to the amino acid sequence designated SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 2, 8, 13, and 18 are drawn to a method of identifying a ligand, an agonist, or antagonist of a genus of ADP-glucose receptors which are at least 70% identical to SEQ ID NO: 2. However, other than the ADP-glucose receptor set forth in SEQ ID NO: 2, the disclosure does not provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure fails to show (i) which portions of SEQ ID NO: 2 are critical for the binding of the receptor to its ligand, agonist or antagonist, or the function activity of the receptor; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 2 will result in protein mutants with the same binding activities and functions as

the polypeptide set forth in SEQ ID NO:2. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Since the instant disclosure fails to provide specific structural information critical to the binding activity or functions of the receptor set forth in SEQ ID NO:2, the disclosure, as a consequence, fails to enable a method of identifying a ligand, an agonist, or antagonist of a genus of ADP-glucose receptors which are at least 70% identical to SEQ ID NO: 2. There are no working examples on how to use the instantly claimed method. The prior art indicates that, at the time when the instant application was filed, there were no ADP-glucose receptors which share at least 70% amino acid identity with the instantly claimed polypeptide set forth in SEQ ID NO:2. Due the complexity of work in this area, it is unpredictable that a polypeptide which shares at least 70% over all amino acid sequence identity with SEQ ID NO:2 will have the same binding or functional activity with the instantly claimed receptor set forth in SEQ ID NO:2. Thus, it would require undue experimentation for one skilled in the art to use the claimed broad method embraced by the instant claims.

Claim Rejections—35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1, 4-7, 10-12, 15-17, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Ames et al. (*IDS*, WO99/57245, November 11, 1999).

Ames et al. teach a method for identifying an agonist, antagonist, or a ligand of the KIAA0001 polypeptide in the presence of ADP-glucose by determining the binding to the polypeptide and by determining a G-protein coupled signal (See, e.g., Abstract; Claims 1, 2, 7, and 8; and pages 16-22 of the specification). The KIAA0001 polypeptide, which shares 43.4% overall amino acid sequence identity with SEQ ID NO:2 (see attached sequence alignment), is a G-protein-coupled receptor for UDP-glucose. Ames et al. also teach detecting a G-protein coupled signal by measurement of intracellular calcium ion concentration (Fig. 4A and line 24 of page 19). While Ames et al. do not explicitly teach to screen “100 or more different candidate compounds”, Ames et al. do teach screening assays using, for example, cells, cell-free preparation, chemical libraries, and natural product mixtures (bottom of page 16). It is, as a matter of choice, to screen a specific number of candidates for one skilled in the art. Thus, the reference of Ames et al. meets limitations of Claims 1, 4-7, 10-12, 15-17, and 20.

Claim Objections

10. Claims 3, 9, 14, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chambers et al. (*IDS, J. Biol. Chem.* 275:10767-10771, 2000) teach a method of identifying a naturally occurring ligand, an agonist, and antagonist for the orphan receptor KIAA0001 by mass screening of large libraries (over 700) of known or putative GPCR ligands.

12. It appears, to the Examiner, that the claims would be free of the prior art if the claimed invention is limited to SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Art Unit: 1646

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
September 14, 2002

Elyseach C. Kenney